7/8/98

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service d1550b

PURGED RK

March 23, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 -18

Mr. Matthew A. Ratliff
President
Loring Labs, Inc.
4360 South County Road 92
St. Bonifacius, MN 55375

Dear Mr. Ratliff:

The Food and Drug Administration (FDA) conducted an inspection of your drug manufacturing facility on January 9, 12, 13, 1998, located in St. Bonifacius, MN. During the inspection our investigators documented found serious violations of the Federal Food, Drug and Cosmetic Act (the Act).

The labeling for your product "*Jamaican Sun* Tan Accelerator" lists "tyrosine" as an ingredient and includes statements such as "Tan Accelerator," and "L-Tyrosine brings the melanin with in your skin to the surface thus accelerating the tan."

The agency (U.S. Food and Drug Administration) states, on page 28293 of the Tentative Final Monograph for Sunscreen Products for Over-The-Counter Human Use published in the May 12, 1993, Federal Register, that any product purporting to "accelerate the tanning process" or "stimulate the production of melanin" is claiming to affect the structure and function of the body and therefore, is a drug [Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)]. We have seen no data demonstrating that tyrosine or its derivatives are safe and effective in stimulating the production of melanin. We are also unaware of any drug labeled

and formulated as these articles are, which was marketed in the United States on or before December 4, 1975. Thus, any product containing tyrosine or its derivative and claiming to accelerate the tanning process is an unapproved new drug [Section 201(p) of the Act] and may not be legally marketed in the United States without an approved New Drug Application [Section 505]. These products are also misbranded in that the labeling fails to bear adequate directions for use for the conditions that are offered [Section 502].

In addition, your product, "***Jamaican Sun*** Tan Accelerator", is adulterated within the meaning of Section 501(a)(2)(B). Our investigators documented significant violations of the Current Good Manufacturing Practices (GMPs) for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 [21 CFR 211] in that:

1. Raw materials are not examined for purity, strength, and quality. In lieu of such testing, no Certificate of Analysis (COA) is received nor is an identity test performed on each component [21 CFR 211.84(d)(2)].
2. The water system is not validated to assure in-process materials and drug products conform to appropriate standards of identity, strength, quality, and purity [21 CFR 211.160(b)].
3. There is no finished product testing to appropriately determine the satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release [21 CFR 211.165(a)].
4. There is no calculation of yield at the conclusion of each appropriate phase of manufacturing, processing, and packaging for each batch of drug product manufactured. Calculations are not performed by one person and independently verified by a second person [21 CFR 211.103].
5. Batch production records lack documentation that each significant step in the manufacture, processing, packing or holding of the batch was accomplished [21 CFR 211.188(b)].
6. No OTC drug product bears an expiration date and there is no stability data to support the exemption for OTC drug products that are stable for at least three (3) years [21 CFR 211.137].

The violations cited in this letter are not necessarily intended to constitute an all-inclusive statement of all of the violations which may exist for products marketed by your firm. You should review the conditions of all your firm's products to

assure they are in compliance with the requirements of the Act. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so they may take this information into account when considering the award of contracts.

You should take prompt action to correct these violations. Failure to promptly correct them may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

You should notify this office in writing within fifteen (15) working days of your receipt of this letter, of the specific steps you intend to take to correct the noted violations. If corrective action cannot be completed within 15 working days, please state the reason for the delay and time frame within corrections will be completed.

Your reply should be sent to Ms. Carrie A. Hoffman, Compliance Officer, at the above address.

Sincerely,

James A. Rahto
District Director
Minneapolis District